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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,175	04/15/2004	R. Kiplin Guy	018062-006310US	9792

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EXAMINER

BARKER, MICHAEL P

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,175	Applicant(s) GUY ET AL.	
	Examiner Michael P. Barker	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) 1-2, 4-12, 16, and 27-28 (in part); 3, 13-15; 17-26; and 29-36 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-36 are pending in the instant application.

Priority

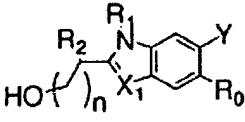
The claim of priority under 35 U.S.C. 119(e) for U.S. Provisional Application No. 60/463,198, filed April 15, 2003, is acknowledged.

Information Disclosure Statements

Applicant has yet to submit an information disclosure statement (IDS).

Response to Election/Restriction Requirement

Applicant's election, with traverse, of Group I, **Claims 1-2, 4-12, 16, and 27-28**, drawn to

compounds and compositions of formula (I), , and specific compound in which **R₀** is methyl, **R₁** is phenethyl, **R₂** is *n*-butyl, **Y** is COOH, and **n** is 0, depicted as Compound 12 of Table 1, is acknowledged. However, Applicant should take note that Table 1 of the Specification recites *Compounds 1 through 6*, and no compound matching the elected species is listed in Table 1. Also, Applicant has failed to define **X₁** in the provisionally elected species. While nonresponsive on its face, Applicant's election and species election does not prevent the application of the rejections discussed *infra*.

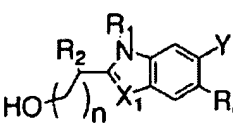
Applicant's traversal is not found persuasive. Groups I and II are directed to or involve the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they

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are patentable over each other. An undue burden is placed on the Examiner regarding Groups I and II since a search for the compounds of formula (I) would not produce references which would anticipate or make obvious the compounds of formula (II), and vice versa.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant maintains the right to file divisional applications on the remaining subject matter. In accordance with M.P.EP 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, the restriction between product claims and process claims is deemed proper. In summary, the restriction requirement put forth October 14, 2005 is maintained as between Groups I-IV, and Groups II-IV will be rejoined when the claims of Group I are found to be in allowable condition.

Scope of the Elected Subject Matter (Subject Matter Searched)

Compounds of formula (I), , as depicted in **Claim 1**, wherein:

- **R₀-R₉** are as defined;
- **m, p, q, and r** are as defined; and
- **Y and Z** are as defined; and
- **W** is as defined, except where W is a heterocyclic group other than five-membered heterocyclic rings with at least one nitrogen (the core compound falls within Class 548, and the heterocyclic groups not encompassed by Class 548 were not searched).

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The scope of Applicant's independent invention, set forth in Group I, encompasses all compounds within the scope of the claims of Group I which fall into the same class as the selected compound. All compounds falling outside the class of the selected compound are heretofore directed to nonelected subject matter and are withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b).

Regarding the scope of compounds set forth above, the compounds are free of prior art and are drawn to allowable subject matter. Amendments to the claims in order to conform with the scope set forth above, to overcome the rejections set forth *infra*, and cancellation of nonelected subject matter will immediately put Applicant's claimed invention in condition for allowance. Applicant preserves the right to file divisional applications on the remaining subject matter.

To summarize, Applicant's Group I as defined in the Restriction Requirement is free of the prior art, and Applicant may, after overcoming the rejections set forth *infra*, elect to accept this patentable group and file divisional applications on the nonelected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 recites the limitation "A compound according to claim 2 in which **R₁** is optionally substituted *phenethyl*." There is insufficient antecedent basis for this limitation in the claim. Specifically, **Claim 1**, on which **Claim 2** is based, does not allow for **R₁** to be phenethyl. This rejection could be overcome by rewriting **Claim 7** in independent form. The

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aforementioned reasoning underlies each of the improper antecedent basis claims which follow and will not be reiterated in each rejection.

Claim 8 recites the limitation, “in which R₁ is 2-hydroxyethyl.” There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation, “in which R₂ is n-butyl, phenyl, or n-butyrylamido.” There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation, “in which R₂ is R₆-X₂-C(R₈)(R₈)-R₇- or R₆-X₂-N(R₈)-R₇-, and the group R₆-X₂-C(R₈)(R₈)-R₇- or R₆-X₂-N(R₈)-R₇- is selected from C₃-C₈ alkyl; C₃-C₆ cycloalkyl; C₃-C₈ alkenyl; -(CH₂)_mC₆H₅ where m is . . .” The groups R₆-X₂-C(R₈)(R₈)-R₇- or R₆-X₂-N(R₈)-R₇- cannot be selected from C₃-C₈ alkyl; C₃-C₆ cycloalkyl; C₃-C₈ alkenyl; etc, as none of these compounds contain nitrogen. X₂, as defined in **Claim 1**, must contain nitrogen. Thus, there is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation, “in which R₁ is phenethyl, R₂ is n-butyl. . .” There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation, “in which R₁ is 2-hydroxyethyl, R₂ is n-butyl. . .” There is insufficient antecedent basis for this limitation in the claim.

Note: Though Group II has not been examined on the merits, similar rejections to those made above, namely insufficient antecedent basis, apply to **Claims 13 and 15**.

Scope of the Nonelected Subject Matter (Not Searched)

As a result of the election and the corresponding scope of the invention identified *supra*, the remaining subject matter of Group I, **Claims 1-2, 4-12, 16, and 27-28**, which is not drawn to

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the above elected invention, as well as the claims of Groups II-IV are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

Telephone Inquiry

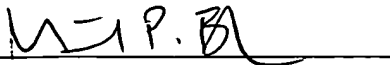
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

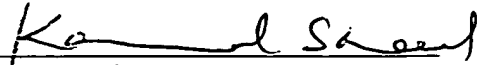
Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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